K002653
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SEP 22 2000

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Submitted by: Mrs. Mitsuko Yoneyama
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Date Submitted: August 18, 2000

Device Identification:

Trade Name:	MMN-1 Coarse Manipulator
Common Name:	Coarse Manipulator
Classification Name:	Assisted Reproduction Micromanipulators and Microinjectors (21 CFR, 884.6150)

Predicate Device:

MMN-1 Coarse Manipulator is substantially equivalent to predicate 3D Manual Coarse Manipulator MN-188NE.

Device Description:

The MMN-1 Coarse Manipulator helps coarse positioning of a microtool under the microscope.

The MMN-1 is a manual driven coarse manipulator and does not require any external power input.

The MMN-1 consists of three sliders and each slider moves in different direction in the respective straight line, X-, Y-, and Z-axis, controlled by X-, Y-, and Z-axis Control Knob, respectively. The MMN-1 is mounted on the microscope and the definition of X-, Y-, and Z-axis is as follows:

- X-axis for X-axis Unit (right-left movement with relation to the microscope)
- Y-axis for Y-axis Unit (front-rear movement with relation to the microscope)
- Z-axis for Z-axis Unit (up-down movement with relation to the microscope)

The MMN-1 Coarse Manipulator is a component part of the micromanipulator system.

A micromanipulator system for the Assisted Reproduction technique, ICSI, requires:
- 1 unit of manipulator mounting adaptor;
- 2 units of coarse manipulator (for coarse positioning) (2 units of the MMN-1);
- 2 units of fine micromanipulator (for fine positioning);
- 2 units of the Universal Joint (for holding the pipette holder);
- 2 units of microinjector (one for holding pipette and one for injecting pipette);
- 1 holding pipette
- 1 injecting pipette

Examples of the role the MMN-1 plays in the system would be:
- coarse positioning of the micropipette into the field of view under the microscope
- coarse positioning of the holding pipette
- coarse positioning of the injecting pipette

Intended Use:

The MMN-1 Coarse Manipulator helps coarse positioning of a microtool under the microscope.

Substantial Equivalence:

Narishige Co., Inc. claims MMN-1 Coarse Manipulator as substantially equivalent to 3D Manual Coarse Manipulator MN-188NE, Premarket Notification 510(k) Number: K001130.

Technological Characteristic:

The MMN-1 Coarse Manipulator is designed compact allowing ample space around the microscope stage.

The MMN-1 is designed for one hand easy operation. Each Control Knob is located close together within reach without much moving the hand.

The movement range of each control is summarized in the table below

X-axis Control Knob :	
Maximum Movement Range	30mm
Y-axis Control Knob:	
Maximum Movement Range	30mm
Z-axis Control Knob:	
Maximum Movement Range	30mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2000

Ms. Mitsuko Yoneyama
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Re: K002653
MMN-1 Coarse Manipulator
Dated: August 18, 2000
Received: August 25, 2000
Regulatory Class: II
21 CFR §884.6150/Procode: 85 MQJ

Dear Ms. Yoneyama:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002653

Device Name: MMN-1 Coarse Manipulator

Indications For Use:

The MMN-1 Coarse Manipulator helps coarse positioning of a microtool under the microscope and is used in assisted reproduction procedures.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002653

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)